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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,054	03/27/2000	NEAL ROSEN	19962YP	9414

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EXAMINER
GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
1614	12

DATE MAILED: 04/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/445,054	Appli ant(s) ROSEN ET AL.	
	Examiner Jerome D Goldberg	Art Unit 1614	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-12,27,30,31 and 33-39* is/are pending in the application.

4a) Of the above claim(s) *12 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 9-11, 27, 31, and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 12 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Applicant's remarks are noted but each synergistic combination is patentably distinct from the other synergistic combination. Applicant's state on page 51 of Paper No. 11, lines 19-24 that "applicants further note that the data provided in the figures in the instant application filed clearly demonstrate an unexpected therapeutic effect from combining a prenyl-protein transferase inhibitor into a microtubule-stabilizing agent." Applicants note that Figures 1-3, 6-12 and 24-27 clearly show that the combination of a prenyl-protein transferase inhibitor with a microtubule-stabilizing agent (taxol or one of the epithilone analogs) results in an activity that is greater than the mere additive effects of the ingredients". Applicants clearly set forth that the combination of ingredients produces a synergistic effect. The instant claims are directed to many synergistic combination (note claim 10 is directed to 210 prenyl-protein transferase inhibitors). The claims read on a multitude of synergistic combination, which would require many field of searches that could be an undue burden on the Examiner. Therefore, the restriction requirement is deemed proper and made FINAL.

Cancellation of non-elected claims and non-elected subject matter from the other claims is now required.

Claims 1-3, 9-11, 27, 31, 34, 35, 36 and 38 are being examined as they read on the elected combination.

Claims 1-3, 9-11, 27, 31 and 33-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancers disclosed, does not reasonably provide enablement for the term "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The term "cancer" in claim 1-3, 9-11, 27, 31 and 33-39 lacks clear exemplary support. Applicants' remarks are noted but the limited number of cancers disclosed on page 18, lines 11-19 would not support such a broad term. Moreover, no sarcomas are disclosed. Claims directed to the specific cancers set forth on page 18, lines 11-19 would overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 9-11, 27, 31 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Anthony et al patent of record taken with the Slichenmyer et al reference of record for the reasons fully set forth in Paper No. 10, pages 4 and 5.

Applicants' remarks that the ". . . combination of prenyl-protein transferase inhibitor with a microtubule stabilizing agent (taxol or one of the epithilone analogs) results in the activity that is greater than the mere additive effects of the ingredients" is noted (page 51, of Paper No. 11, lines 22-24) but the claims fail to recite a greater than additive effect. Claims directed to a greater than additive effect would overcome this rejection.

Claims 1-3, 9, 27, 31 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific prenyl-protein transferase inhibitor disclosed, does not reasonably provide enablement for the term "prenyl-protein transferase inhibitor". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The term "prenyl-protein transferase inhibitor" in claims 1-3, 9, 27, 31, and 33 lacks clear exemplary support. Applicants' remarks are noted but the term is so broad that even the large number of examples set forth will not support such a broad term. Moreover, it is not apparent that all examples will produce a synergistic effect.

Claims 1-3, 10, 11, 27, 31, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific antineoplastic agent which is a microtubule-stabilizing agent disclosed, does not reasonably provide enablement for the term "an antineoplastic agent which is a microtubule-stabilizing agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The term "an antineoplastic agent which is a micro tubule-stabilizing agent" in claims 1-3, 10, 11, 27, 31, 34 and 35, lacks clear exemplary support in the specification as filed. Applicants' remarks are noted but time limited number of examples will not support such a broad term. Moreover, it is not apparent that all the examples will produce a synergistic effect.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday- Thursday 9 am - 3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 3053592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg: mv
April 22, 2002

JEROME D. GOLDBERG
PRIMARY EXAMINER